UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,238	12/29/2006	Arthur Zwingenberger	70566-0021US	5112
22902 CLARK & BRO	7590 06/24/200 ODY	EXAMINER		
	NT AVENUE, NW	MCADAMS, BRAD		
SUITE 250 WASHINGTON, DC 20005			ART UNIT	PAPER NUMBER
			2152	
			MAIL DATE	DELIVERY MODE
			06/24/2008	PAPER

# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No. Applicant(s)				
	10/576,238	ZWINGENBERGER ET AL.			
Office Action Summary	Examiner	Art Unit			
	ROBERT MCADAMS	4134			
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
Status					
Responsive to communication(s) filed on <u>05 Mar</u> This action is <b>FINAL</b> . 2b) ☑ This      Since this application is in condition for allowant closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro				
Disposition of Claims					
4) ☐ Claim(s) 1-4 and 6-19 is/are pending in the apprending of the above claim(s) 4 is/are withdrawn fro  5) ☐ Claim(s) is/are allowed.  6) ☐ Claim(s) 1-4 and 6-19 is/are rejected.  7) ☐ Claim(s) is/are objected to.  8) ☐ Claim(s) are subject to restriction and/or  Application Papers	om consideration.				
9) ☐ The specification is objected to by the Examiner 10) ☑ The drawing(s) filed on 05 May 2006 is/are: a) ☐ Applicant may not request that any objection to the o Replacement drawing sheet(s) including the correction 11) ☐ The oath or declaration is objected to by the Examiner	☑ accepted or b)☐ objected to be drawing(s) be held in abeyance. See on is required if the drawing(s) is obj	e 37 CFR 1.85(a). lected to. See 37 CFR 1.121(d).			
Priority under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>					
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date See Continuation Sheet.	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	nte			

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/13/2007, 02/21/2007, 05/05/2006.

#### **DETAILED ACTION**

## Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2, 6-15 and 19 are rejected under 35 U.S.C. 102(b) as being unpatentable over PCT Pub No. WO01/94016 by *Veitch et al (Veitch)*.

As to Claim 1 and 2, Veitch discloses collecting process information relating to processing content (Sample information data is collected during the processing of a sample. Page 12, Lines 1-5) from an indicator on a device (RFID tag 220, Figure 3) used in a sterilization facility (Autoclave; Page 4, Lines 21-30) via a computer network (Sample information collected is transferred to an electronic database via a wireless network. Paragraph bridging page 12 and 13);

storing the information electronically to allow for the generation of displays based on the received information (The electronic database stores information data and includes a display for clients to view the display of data. Page 8, Lines 29-31, Page 9, Lines 1-6).

As to **Claim 6**, *Veitch* further discloses a cassette for storing said device (10, Figure 1a, 1b), said cassette having an electronically readable cassette tag (20, Figure 1a, 1b), storing information regarding said device on said cassette

tag, and placing said device in said cassette (RFID tag 20 contains serial numbers and any details about a device placed in the cassette. Page 11, Lines 11-15).

As to **Claims 7 and 8**, *Veitch* further discloses said step of storing information regarding said device comprises optically scanning a code on said device (The carrier contains a barcode for further means of identification. Page 5, Lines 4-8)).

As to **Claim 9**, *Veitch* further discloses establishing a link between the plurality of contact points to allow retrieval of the stored information (Each plurality of RFID tags in rack 350 contains a unique identifier to allow retrieval of stored information on said tag. Paragraph bridging Page 12 and 13).

As to **Claim 10**, *Veitch* further discloses wherein the step of collecting includes identifying an instrument as the device (The reader reads the unique identifier from the RFID tag for identification. Page 12, Lines 14-24).

As to Claim 11, Veitch further discloses electronically reading status information from an indicator at a plurality of contact points relating to a sterilization condition of an instrument; and storing the information electronically on a RFID tag (Status information from sample containers 410 are read and stored on RFID tag 420. Paragraph bridging 13 and 14).

As to **Claim 12**, *Veitch* further discloses an RFID tag configured to receive, record, store and make available for subsequent electronic transmission information relating to an instrument to be sterilized (Sample containers 310 have

Application/Control Number: 10/576,238

Art Unit: 4134

an RFID tag which receive, record, store and make available information relating to the sample. Paragraph bridging Page 12 and 13).

Page 4

As to **Claim 13**, *Veitch* further discloses wherein said information comprises the serial number of said container (Page 11, Lines 11-14).

As to **Claim 14**, *Veitch* further discloses a tag in combination with said container for a plurality of said instruments (RFID tag 420 is attached to sample container 410 holding samples in each container. Page 13, Lines 15-19).

As to **Claim 15**, *Veitch* further discloses a tray (10) for receiving said plurality of instruments to be sterilized, a lid (15) for covering said tray and forming an enclosure, and a seal (15) between said tray and lid for sealing said enclosure and having at least a portion of said tag embedded therein (Figure 1b).

As to Claim 19, Veitch further discloses a tag in combination with an Autoclave for sensing and indicating a sterilization process to which an instrument has been subjected comprising: a power supply, a switch for determining when a predetermined temperature and/or pressure condition has been reached and for activating said power supply in response thereto, a sensor for detecting sterilization temperature and/or pressure conditions at a contact point, and a central processing unit for processing the information from the sensors and writing said information to said RFID tag for subsequent retrieval (Page 4, Lines 21-30).

Application/Control Number: 10/576,238 Page 5

Art Unit: 4134

## Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Veitch et al (Veitch)* in view of PG Pub No. US 2004/0174261 A1 by *Volpi et al (Volpi)*.

As to **Claims 3-4**, *Veitch* does not expressly disclose a network client associated with an authorized reviewer.

Volpi further discloses wherein the network client is associated with an authorized reviewer that analyzes that data to evaluate compliance with sterilization processing standards (Authorized users use the Extranet to evaluate internal information. Paragraph 0057).

Veitch and Volpi are analogous art because they are form the same field of endeavor with respect to RFID and medical devices.

At the time of invention, it would have been obvious to a person of ordinary skill in the art to use an authorized reviewer to evaluate compliance with sterilization processing standards. The motivation would have been to assure correct processing standards.

5. **Claims 16-18** are rejected under 35 U.S.C. 103(a) as being unpatentable over *Veitch* in further in view of U.S. Patent No. 6,454,162 B1 by *Teller*.

Application/Control Number: 10/576,238 Page 6

Art Unit: 4134

As to **Claims 16-18**, *Veitch* discloses a tag in combination with a seal configured to fit between a tray and a lid (Figure 1b).

Veitch does not expressly disclose a tag at least partially embedded in said seal and wherein said tag is capable of accumulating the number of sterilizing procedures in which said seal has been used.

Teller discloses a tag at least partially embedded in said seal and wherein said tag is capable of accumulating the number of sterilizing procedures in which said seal has been used (An RFID tag is embedded in the medical item 30 and accumulates the number of procedures used. Column 2, Lines 51-55).

Veitch and Teller are analogous art because they are form the same field of endeavor with respect to RFID and medical devices.

At the time of invention, it would have been obvious to a person of ordinary skill in the art to embed the tag in the seal to accumulate the number of procedures performed. The motivation would have been to assure proper procedure.

Application/Control Number: 10/576,238 Page 7

Art Unit: 4134

#### Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT MCADAMS whose telephone number is (571)270-3309. The examiner can normally be reached on Monday-Thursday 6:30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lun-Yi Lao can be reached on 571-272-7671. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ROBERT MCADAMS/ Examiner, Art Unit 4134

/LUN-YI LAO/ Supervisory Patent Examiner, Art Unit 4134